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## HEPATOTOXICITY IN INJECTION DRUG USERS (IDUS) AND NON-IDUS RECEIVING NEVIRAPINE-BASED HAART

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**BACKGROUND:** Hepatotoxicity is a frequent cause of interruption of antiretroviral therapy especially in IDUs co-infected with HCV. We have measured the incidence of hepatotoxicity in IDUs receiving HAART and its effect on treatment outcome and compared these parameters to those measured on non-IDUs.

**METHODS:** HIV-infected IDUs and non-IDUs initiating nevirapine-based HAART (along with 2 NRTIs) as the first NNRTI-based regimen were included in this retrospective, comparative study. ALT and AST levels were evaluated at baseline and at months 1, 3, 6, 9 & 12, hepatotoxicity being defined as a single value  $> 5 \times$  ULN (grade 3 or 4 toxicity).

**RESULTS:** A total of 162 subjects (80 IDUs, 54 males; 82 non-IDUs, 76 males) were included in the analysis. At entry, 32% of patients were drug-naïve, with 94% IDUs and 30% non-IDUs being HCV-positive. Grade 3/4 ALT and AST elevations at any time point were 11% and 13% in IDUs and 13% and 9% in non-IDUs, respectively ( $p > 0.05$  for all comparisons). Cumulative treatment discontinuation rate at month 12 due to hepatotoxicity was 9% in IDUs and 9% in non-IDUs with no deaths due to hepatic failure registered during this period. Using a Cox Proportional Hazard model,  $>$  grade 2 hepatotoxic events were associated with HCV infection (HR=9.0, 95% CI: 2.5-33.3,  $p < 0.001$ ), being naïve to HIV therapy (HR=3.7, 95% CI: 1.5-9.2,  $p = 0.005$ ), and having baseline ALT  $>$ ULN (HR=3.8, 95% CI: 1.0-13.5,  $p = 0.04$ ). When adjusting for these risk factors, IDUs were less likely to experience grade 3/4 hepatotoxicity (HR=0.2, 95% CI: 0.07-0.57,  $p = 0.002$ ).

**CONCLUSIONS:** Clinically significant hepatotoxicity occurred in 15% IDUs and 15% non-IDUs. HCV-infection, being naïve to HAART and abnormal baseline ALT were associated with higher risk of hepatotoxicity. Application of these criteria will allow us to define a population of IDUs and non-IDUs in whom nevirapine-based therapy can be safely prescribed.

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